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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,674	10/12/2001	Steve Oi	70669	1084

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/16/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/976,674

Applicant(s)

OI ET AL.

Examiner

Malgorzata A. Walicka

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-43 is/are pending in the application.
- 4a) Of the above claim(s) 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-32 and 35-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: sequence alignment.

The Amendment and Response filed on May 21, 2003, as paper No. 11 is acknowledged. The amendments to the claims have been entered as requested. Claims 1-21 are canceled. New claims 22-43 have been entered. Claims 22-43 are the subject of this Office Action.

### **Detailed Office Action**

#### ***1. Objections***

##### ***1.1. Oath***

As indicated in the previous Office Action, paper No. 8, the oath or declaration is defective, because it misses the date of filing the utility application.

#### ***2. Restriction/election***

Newly submitted claims 32, 33 and 34 are directed to an invention that is independent or distinct from the invention originally elected , because the Applicant elected, in paper No. 7, filed on Nov. 4, 2002, to prosecute claims 1-6 and 8-13 directed to DNA of SEQ ID NO: 4 encoding protein of SEQ ID NO: 3. The newly filled claims 22-43 are directed to the following inventions:

- I. Claim 22-31 and 35-43, drawn to isolated nucleic acid of SEQ ID NO: 4 or encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 3, expression vector, host cell and the method of producing polypeptides that comprises SEQ ID NO: 3 classified in class 435, subclass 212.

Art Unit: 1652

- II. Claim 32, 33 and 34, all in part, drawn to SEQ ID NO: 24, classified in class 536, subclass 23.2.
- III. Claim 32 and 33 both in part, drawn to SEQ ID NO: 26, classified in class 536, subclass 23.2.
- IV. Claim 32, 33 and 34, all in part, drawn to SEQ ID NO: 28, classified in class 536, subclass 23.2.
- V. Claim 32 and 33, both in part, drawn to SEQ ID NO: 30, classified in class 536, subclass 23.2.
- VI. Claim 32, 33 and 34, all in part, drawn to SEQ ID NO: 34, classified in class 536, subclass 23.2.
- VII. Claim 32 and 33, both in part, drawn to SEQ ID NO: 36, classified in class 536, subclass 23.2.
- VIII. Claim 32, 33 and 34, all in part, drawn to SEQ ID NO: 38, classified in class 536, subclass 23.2.
- IX. Claim 32 and 33, both in part, drawn to SEQ ID NO: 40, classified in class 536, subclass 23.2.

Inventions I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, DNA molecules of SEQ ID NO: 4, 24, 26, 28, 30, 34, 36, 38, and 40 are divergent molecules having different chemical structures. As

Art Unit: 1652

to their enzymatic activities, Applicants provided an evidence that DNA of SEQ ID NO: 4 encodes protein of SEQ ID NO: 3 having the activity of dipeptidyl peptidase. This, however, does not mean that polypeptides encoded by SEQ ID NO: 24, 26, 28, 30, 34, 36, 38, and 40 have the same enzymatic activity as the polypeptide encoded by SEQ ID NO: 3, because although these DNA molecules are splice variants of the same primary transcript of undisclosed genomic sequence, the proteins they encode may have different biological functions and effects. In addition, SEQ ID NO: 4, 24, 26, 28, 30, 34, 36, 38, and 40 are not disclosed as capable of use together. For these reasons the restriction between Groups I-IX is proper.

The Applicant elected, in paper No. 7, filed on Nov. 4, 2002, to prosecute original claims 1-6 and 8-13 directed to DNA of SEQ ID NO: 4 encoding protein of SEQ ID NO: 3. Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 32, 33 and 34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### **3. Rejections**

#### **3.1. 35 U.S.C. 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1652

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 22-31, 35-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "(a) a polypeptide which includes" in claim 22 should be replaced by "(a) a polypeptide comprising". Also, the term "having" in part (b) of claim 22 is confusing, because it is unknown whether the Applicants' intention is to claim a polypeptide set forth by an amino acid sequence that is at least 90% similar to SEQ ID NO: 3 or a polypeptide comprising an amino acid sequence that is at least 90% similar to SEQ ID NO: 3.

Claims 24-26 are confusing because the claims erroneously identify the nucleotide sequence as SEQ ID NO: 3. SEQ ID NO: 3 is an amino acid sequence.

Claim 22 and 35 is reciting the phrase "a shortened fragment" which is indefinite, because it is unknown what a shortened fragment is. The examiner suggests the following language for claim 35:

An isolated nucleic acid which encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 3 or a fragment thereof exhibiting polyl oligopeptidase activity or which is complementary thereto.

Claims 27 and 39 are confusing, because they recite: "SEQ ID NO: 3 operably linked to a promoter." SEQ ID NO: 3 is an amino acid sequence and as such cannot be linked to any promoter. The examiner suggests the following language for claim 39: "An expression vector comprising the nucleic acid of claim 35 encoding a polypeptide having the entire amino acid sequence set forth in SEQ ID NO: 3, wherein said nucleic acid is operably linked to a promoter."

Claims 27 and 39 are also confusing as to whether they recite vectors or transformed hosts, because the phrase "said expression vector being present in a compatible cell" appears to require a host, however, the preamble recites "An expression vector".

Claim 29 and 41 are rejected for recitation of the phrase "at least the mature portion of the amino acid sequence of SEQ ID NO: 3." Applicants do not disclose the signal sequence and or other pro-sequence included in the polypeptide of SEQ IDNO:3, thus the sequence of the mature form is also unknown.

### **3.2. 35 USC section 112, first paragraph**

#### **3.2.1. Lack of written description**

##### **Rejection withdrawal**

Original claims 1-6 and 8-13 were rejected in the previous Office Action, paper No.8, under 35 U.S.C. 112, first paragraph, because lack of written description of SEQ

Art Unit: 1652

ID NO: 3. The examiner acknowledges the amendment to Table I, which removes the ambiguity in description of SEQ ID NO: 3. Thus rejection for ambiguity in description of SEQ ID NO: 3 is withdrawn.

New claims 29, 30, 31 and 41-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite the DNA molecule encoding a mature portion of the amino acid sequence of SEQ ID NO: 3. The disclosure, however fails to teach the mature form of SEQ ID NO: 3 by disclosing its amino acid sequence, or the DNA molecule encoding it. The specification does not teach which part of SEQ ID NO:3 is a signal portion of the protein that carries it to the cell membrane and/or other pro-sequence.

Taking into account lack of identifying structural characteristics of the claimed DNA molecule one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

### **3.2. 35 USC section 102**

#### Withdrawal rejection over sequences disclosed by Lamerdin et al.

Rejection of original claims 1, 2, 6, 8, 9 under 35 U.S.C. 102(b) as being

Art Unit: 1652

anticipated by Lamerdin, J. E. et al. (1998) made in the previous Office Action is moot because the claim has been cancelled. The Lamerdin's sequences do not anticipate the instant inventions for the reasons presented by Applicants in their Response, paper No. 11.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 22-23, ~~28~~<sup>and</sup>, 35-36 and ~~40~~ are rejected under 35 U.S.C. 102(e) as being anticipated by the US Patent No. 6,569,662 (the patent) issued on May 27, 2003, filed as US Application No. 09/620,317 on July 19, 2000.

Art Unit: 1652

The claims are directed to a polypeptide having an amino acid sequence that is at least 90% similar to SEQ ID NO: 3, or to a fragment of SEQ ID NO: 3, wherein the amino acid sequence and fragment exhibit prolyl oligopeptidase activity.

The patent comprises SEQ ID NO: 99 that is 2801 nucleotides long and encodes a protein that is in 94.3% similar to SEQ ID NO: 3. SEQ ID NO: 99 comprises in positions 2362-2381 the nucleotide sequence encoding amino acid sequence GWSYG which is the active site of the prolyl oligopeptidase activity of SEQ ID NO: 3; see Fig. 1B of the instant application. In addition, SEQ ID NO: 99 encodes a continuous fragment of SEQ ID NO: 3 comprising amino acid residues 610-832. Thus, SEQ ID NO: 99 of the patent anticipates claims 22-23 and 35-36 of the instant application.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

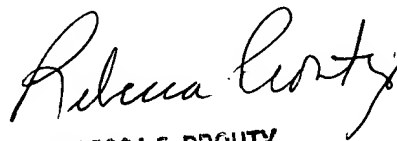
If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

Art Unit 1652

Patent Examiner

  
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1652